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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
VANDER VEGT, F	
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ARENT FOX KINTER PLOTKIN & KAHN, PLLC
1050 CONNECTICUT AVENUE, N.W.
SUITE 600
WASHINGTON DC 20036-5339

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/817,704	Applicant(s) Swaak
	Examiner F. Pierre VanderVegt	Art Unit 1644

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 26, 2001*

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *14-16, 18-26, 30, and 31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *14-16, 18-26, 30, and 31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

This application is a rule 371 continuation of PCT/NL95/00370.

Claim 17 has been canceled.

Claims 14-16, 18-26 and 30-31 are currently pending in this application.

Specification

1. The disclosure is objected to because of the following informalities:

Applicant should scan the specification for misspellings and typographical errors. For example, at page 4, line 2, the word "leval" should be replaced with --level--.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

2. Claims 14-16, 20-22, 25, 26 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The paper filed September 26, 2000, now entered pursuant to Applicant's request in the RCE filed February 26, 2001, amends claim 14 to now recite "wherein the patient does not have anemia." constitutes new matter. The negative limitation is not supported by any statement in the specification suggesting such a limitation for practice of the invention and was added merely in an attempt to differentiate the invention from the prior art of record. See *Ex parte Grasselli*, 231 U.S.P.Q. 393, 394 (PTO Bd. App. 1983). Applicant contends that the limitation affecting claims 14-16, 21 and 22 is supported by the instant specification at page 3, lines 34-35. The Examiner respectfully disagrees. The statement in the specification is not present as any kind of limitation to exclude anemic patients, rather it is a cautionary statement indicating that special care must be taken when treating patients who are not anemic.

The recitations of "period comprises 3 weeks of treatment" in base claim 20 and "comprises 6 weeks of treatment" in claim 31 were not disclosed in the claims or specification as

originally filed and constitutes new matter. While the specification discloses particular effects of the method being notable at the 3 and 6 week time points, the term "comprises" is an open term which encompasses a period of treatment for an indeterminate period of time, IE, no endpoint, and this is not disclosed in the instant specification.

3. Claims 14-16 and 21-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to methods of "treating chronic inflammation in a patient in need thereof" (base claim 14). It is noteworthy that most diseases as well as surgical procedures are associated with inflammation. One with skill in the art would not expect to be able to use erythropoietin products to treat chronic inflammatory diseases in general. Erythropoietin is a humoral regulator of erythropoiesis and stimulates the production of erythrocytes. It is used to treat diseases associated with anemia in order to increase the production of red blood cells. Pages 4-5 of the specification speculate that erythropoietin may exert anti-inflammatory effects either by mobilizing iron to hemoglobin production and away production of hydroxy-radicals associated with tissue damage in diseases like arthritis. Another suggested mechanism is the role EPO may have on Th1/Th2 balance and on particular cytokines. The sole exemplification of the claimed invention in the specification indicates that EPO treatment of subjects certified to have chronic anemia (ACD) associated with rheumatoid arthritis (RA) (page 6, lines 3-11 for example) resulted in certain clinical improvements, including reductions in pain score and morning stiffness and improvement in well-being. One with skill in the art would not have had a reasonable expectation of treating diseases other than RA with ACD using EPO because of the complexity of the physiological mechanisms of different autoimmune diseases. Phenomena such as abnormal iron or cytokine levels associated with RA with ACD would not reasonably be expected to occur in other autoimmune or inflammatory diseases. Robbins, Pathological Basis of Disease, page 190 (of

record) indicated that "Although it would be attractive to explain all autoimmune diseases by a single mechanism, it is now clear there are a number of ways by which tolerance can be bypassed" and defects associated with autoimmune diseases differ from one disorder to another. Therefore, it would have been unpredictable whether treatment of subjects having other autoimmune or inflammatory disorders with EPO would result in clinical improvement. The specification indicates that administration of EPO results in reductions in pain, morning stiffness and well-being for arthritis patients, but does not evidence that EPO treats other chronic inflammatory diseases. Applicant need not evidence that every possible inflammatory disease may be treated by EPO in order to support a generic claim, see In re Cook and Merigold, 169 USPQ 298 (CCPA 1971) and In re Cavallito and Gray, 127 USPQ 202 (CCPA 1960). However, evidence that a reasonable number of species of chronic inflammatory diseases are treatable with EPO would be required and a single example of treating a group of patients who all have RA with ACD is not representative for enablement of broad claims.

Claim Rejections - 35 U.S.C. §§ 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 18-20 and 23-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Toshihide et al (U2 on form PTO-892, English abstract only).

The Toshihide et al reference teaches that the treatment of rheumatoid arthritis patients with anemia using erythropoietin for a period of three weeks. Toshihide et al teaches the alleviation of a symptom of the disease in that the patients experienced a significant increase in erythropoiesis. While Toshihide et al does not specifically teach that the patients experienced a decrease in stiffness, pain or swelling, an increase in grip strength, or change in C-protein sedimentation rate, Applicant is reminded that silence about a particular feature does not constitute its absence. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable (In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977)). In Bristol-Myers Squibb Company v. Ben Venue Laboratories 00-1304 (CAFC 4/20/01) the Federal Circuit upheld a summary judgment of invalidity of most claims in two Bristol patents. The patents are for methods of administering a specific amount of TAXOL over a period of about three hours to treat tumors. An earlier publication described the same method, but the person performing the method earlier did not detect any anti-tumor effect on patients. The Federal Circuit agreed Bristol's claims are anticipated by the earlier publication under patent code section 102(b) even though the Bristol claims recite the result of affecting tumors. The court said, "Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." See also MPEP 2112-2112.02. Accordingly, the instant treatment with erythropoietin and the treatment taught by Toshihide et al appear to be the same or similar absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the materials, i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious.

In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed materials are different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

5. Claims 18-20, 23-26 and 30-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Petterson et al (V2 on form PTO-892).

The Petterson et al reference teaches that the treatment of rheumatoid arthritis patients with anemia using erythropoietin for a period of 3 to 17 weeks. Petterson et al teaches the alleviation of a symptom of the disease in that the patients experienced relief of their anemia. Petterson et al further teaches that severe inflammation slowed response to erythropoietin, warranting longer treatments. While Petterson et al does not specifically teach that the patients experienced a decrease in stiffness, pain or swelling, an increase in grip strength, or change in C-protein sedimentation rate, Applicant is reminded that silence about a particular feature does not constitute its absence. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable (In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977)). In Bristol-Myers Squibb Company v. Ben Venue Laboratories 00-1304 (CAFC 4/20/01) the Federal Circuit upheld a summary judgment of invalidity of most claims in two Bristol patents. The patents are for methods of administering a specific amount of TAXOL over a period of about three hours to treat tumors. An earlier publication described the same method, but the person performing the method earlier did not detect any anti-tumor effect on patients. The Federal Circuit agreed Bristol's claims are anticipated by the earlier publication under patent code section 102(b) even though the Bristol claims recite the result of affecting tumors. The court said, "Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." See also MPEP 2112-2112.02. Accordingly, the instant treatment with erythropoietin and the treatment taught by Petterson et al appear to be the same or similar absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual

evidence needed in order to establish that there is a difference between the materials, i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious.

In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed materials are different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Conclusion

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

7. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2001 365-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
May 16, 2001

F. PIERRE VANDERVEGT
PATENT EXAMINER